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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,066	11/07/2001	Scott L. Diamond	3936-011568	3883

7590 11/20/2006

Barbara E. Johnson
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818

EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,066	DIAMOND, SCOTT L.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims in claim 10 a computer and a set of operating instructions resident in computer software of the computer for operating: a set of applicator pins and a separate device for biological sample aerosol mist generation. However, the specification does not disclose that the same computer and same software is used to control both the applicator pins and the separate device for aerosol mist generation. The specification on page 12 only recites that a software can control the subcomponents of the assay device and lists the subcomponents of the device but does not include the applicator pins as part of the subcomponents of the device. Similarly, claims 11 and 12 do not list the applicator pins as being "subcomponents".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites "a computer and a set of operating instructions resident in computer software of the computer for operating: a set of reactant dot applicator pins; a separate device for biological sample aerosol mist generation; an xy positioner operatively connected to the dot applicator pins; a chamber...." It is not clear whether or not the same computer and instructions in a software are utilized to operate the dot applicator pins as well as the device for aerosol mist generation and xy positioner. For examination purposes, the claim will be interpreted to mean that different computer and software operate these devices. Also, it appears from claim 10 that the computer and instructions in a software are operating the chamber; but it is not clear how they are operating the chamber. (This interpretation does not appear to be Applicant's intention and will not be interpreted so for examination purposes.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al., 6,573,369, in view of Eipel et al., 6,737,024, and further in view of Engle et al., 6,521,325.

Henderson et al. disclose the invention substantially as claimed. More specifically, Henderson et al. disclose an assay system comprising :

a first set of computer-controlled reactant dot applicators (AFM, col. 12, line 33);

a computer-controlled xy positioner (i.e., deposition instrument, col. 9, line 49);

a computer and operating software (col. 9, lines 51-52 and col. 12, lines 33-36); and

The Office notes that Henderson et al. teach that the AFM device can deposit as little as a single macromolecule (col. 13 lines 19-20) and that the center of one molecular domain to the center of the next domain may be as small or smaller than one micron (col. 13, lines 41-44). Thus, the AFM device is capable of creating dots having a diameter ranging from 10 microns to 100 microns, and is capable of creating dots that

are not covalently bound to a substrate (e.g., the dots can be adsorbed), as claimed by Applicant. The AFM can produce an array on a substrate (col. 13, lines 19-25). Henderson et al. teach that the array may be utilized on site or shipped to another location for exposure of the array to a sample medium (col. 13, lines 22-27). However, Henderson et al. do not teach that the array may be exposed to a sample medium using an aerosol generation device as claimed by Applicant.

More specifically, Henderson et al. do not teach a computer-controlled aerosol generation device (nor a chamber for control of biological samples, which the Office interprets to be in the aerosol generation device) wherein the first set of computer-controlled reactant dot applicators are capable of creating a plurality of reaction spots to which the aerosolized biological sample droplets are applied simultaneously by said second, separate computer-controlled device for sample aerosol generation for computer-enhanced assay of any reaction between the sample droplets and the dot constituents. However, Eipel et al. teach such an aerosol generation device.

Eipel et al. teach that ink jet printers may be used to apply sample material and reagents to a support (col. 4, lines 32-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a printer as taught by Eipel et al. with the Henderson array because Eipel et al. teach that a printer may be used to apply sample materials and reagents to a support, such as the Henderson support containing an array. The Eipel et al. printer is capable of applying droplets simultaneously to the reactant spots of the Henderson et al. device because a printer such as that disclosed by Eipel et al. ejects more than one molecule and the Henderson

et al. device can place as little as a single molecule on each domain and that the domains can be smaller than one micron apart.

The Office notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the prior art structure is capable of performing the intended use. In this case, the Eipel et al. device is capable of applying droplets simultaneously to the reactant spots as described above, and without forming a wetting film. It is noted that the distance between the dots is not recited. It is also noted that Eipel et al. teach ink jet printers can eject very small drops (col. 4, lines 37-47). Thus, the ink jet printers can apply droplets without forming a wetting film, especially if the spots are far apart. Because Applicant is claiming a device, the prior art device only needs to be capable of performing the claimed intended use. The Eipel et al. ink jet printer is capable of producing fine particles of liquid and thus is capable of producing an aerosolized mist. Also, it is noted that Applicant's claim 12 recite ink jet printheads to be a device for aerosol mist generation.

However, the above references also do not teach clearly that the printer is computer-controlled, nor do they clearly teach a set of operating instructions in a computer software. Engle et al. teach these limitations.

Engle et al. teach that a computer, software and printer will control the size, number and placement of the drops (col. 2, lines 23-24), which may be biological fluids

or chemical assay reagents (see abstract, second sentence). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a computer and software as taught by Engle et al. for the Eipel et al. printer because Engle et al. teach that a computer and software can control the size, number and placement of drops, as would be desirable for convenience.

As to claims 11 and 12, the claimed system contains a subcomponent (i.e., ink-jet printer, see Eipel et al., col. 4, lines 32-40.)

2. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al., 6,573,369, in view of Tisone, 5,738,728, and further in view of Engle et al., 6,521,325.

Henderson et al. disclose the invention substantially as claimed. More specifically, as to claim 10, Henderson et al. disclose an assay system comprising :

a first set of computer-controlled reactant dot applicators (AFM, col. 12, line 33);

a computer-controlled xy positioner (i.e., deposition instrument, col. 9, line 49);

a computer and operating software (col. 9, lines 51-52 and col. 12, lines 33-36); and

a chamber (col. 11, lines 60-62, disclosing the immersion of the tip of the probe device in a solution; the element containing the solution is considered the claimed chamber) for control of biological samples.

The Office notes that Henderson et al. teach that the AFM device can deposit as little as a single macromolecule and that the AFM can produce an array on a substrate (col. 13, lines 19-25). Henderson et al. teach that the array may be utilized on site or shipped to another location for exposure of the array to a sample medium (col. 13, lines 22-27). Henderson et al. also teach that the array may be dipped in a solution or exposed to a gas (col. 14, lines 33-34). However, Henderson et al. do not teach that the array may be exposed to a sample medium using an aerosol generation device as claimed by Applicant.

More specifically, Henderson et al. do not teach a computer-controlled aerosol generation device wherein the first set of computer-controlled reactant dot applicators are capable of creating a plurality of reaction spots to which the aerosolized biological sample droplets are applied simultaneously by said second, separate computer-controlled device for sample aerosol generation for computer-enhanced assay of any reaction between the sample droplets and the dot constituents. However, Tisone teaches such an aerosol generation device.

Tisone teaches a plurality of syringe pumps mounted on an apparatus for aerosolizing reagents onto a support (col. 3, lines 15-28, and col. 5, lines 55-59, and col. 8, lines 24-25) in a controlled and exacting manner (col. 3, lines 21). (The syringe

pump taught by Tisone is considered to be a microsyringe pump, as claimed by Applicant, because it is small, see col. 5, lines 65-66.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a syringe pump as taught by Tisone with the Henderson array because Tisone teaches that syringe pumps may be used to apply sample materials and reagents to a support, such as the Henderson support containing an array, in a controlled and exacting manner. The Office notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the prior art structure is capable of performing the intended use. In this case, the Tisone device is capable of applying droplets simultaneously to the reactant spots as described above.

Moreover, Tisone teaches a set of operating instructions resident in computer software and that the aerosol generation device is computer controlled. That is, Tisone teaches that the dispensing apparatus may be integrated to an X-Y platform to coordinate delivery of the reagent (col. 7, lines 44-48). A microprocessor controls the platform and syringe pump (col. 7, lines 54-57). As to claims 11 and 12, the claimed subcomponent is the X-Y platform (i.e., the claimed xy positioner system in claim 12, line 6).

However, Tisone does not teach a software for operating the syringe pumps.

Engle et al. however teach that a computer, software and printer will control the size, number and placement of the drops (col. 2, lines 23-24), which may be biological fluids or chemical assay reagents (see abstract, second sentence). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a software, in addition to a computer, as taught by Engle et al. for the Tisone syringe pumps because Engle et al. teach that a computer and software can control the size, number and placement of drops, as would be desirable for convenience.

As to claim 13, the microsyringe pumps disclosed by Tisone are considered the claimed microsyringes. The microsyringes are capable of holding 1 microliter of biological sample (col. 7, line 51.)

As to claim 14, the microsyringes are capable of delivering samples at a constant flow rate (and col. 6, lines 38-42, and col. 7, lines 53-57.)

3. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al., 6,573,369, in view of Tisone, 5,738,728, as applied to claim 10 above, and further in view of French et al., 5,345,079.

Henderson et al. in view of Tisone disclose the invention substantially as claimed (see claim 10 above), except for the device for aerosol generation being an ultrasonic nebulizer. French et al. teach this limitation.

French et al. teach that a device for analysis of a sample utilizing a droplet source that can be a micro pump or any form of conventional nebulizer, such as a spray

nebulizer, or ultrasonic nebulizer (col. 17, lines 3-6.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute an ultrasonic nebulizer as taught by French et al. for the Tisone spraying device because French et al. teach that ultrasonic nebulizers are functional equivalents of spraying devices, such as the Tisone spraying device, for applying a material to a substrate for analysis.

Response to Arguments

Applicant's affidavit and response filed August 28, 2006 have been considered but are not persuasive.

Applicant asserts in the affidavit as well as the response that never has it been possible before the present invention to deliver an aerosolized mist to droplets in which each droplet has a diameter ranging between 10 mm and 100mm and separated only by a center to center distance of only 50 mm to 500 mm, without cross-contaminating the droplets or changing the position of each droplet. It is noted that the claims only recite that the dots have a diameter ranging from 10 microns to 100 microns, and the claims do not recite the distance between the dots. It is emphasized that Applicant is claiming a device and thus the prior art device only needs to be capable of performing the intended use. The Eipel et al. reference teach an ink jet printer which is capable of delivering an aerosolized mist. It is also noted that Applicant's claim 12 recite ink-jet printheads, among other apparatuses such as microsyringe pumps, as being the device

for biological sample aerosol mist. Thus, the Eipel et al. ink jet printer meets Applicant's recitation of a device for biological sample aerosol mist generation.

Applicant also asserts in the affidavit as well as the response an unexpected finding of generation of an aerosolized mist that is so fine so as to deposit the aerosolized mist on any array to mix with the droplets while at the same time evaporating very rapidly such that cross-contamination of the droplets is prevented. However, as indicated above, the Eipel et al. reference meets the limitation of being capable of producing an aerosolized mist to dots having a diameter ranging from about 10 to 100 microns without forming a wetting film. It is noted that the distance between the dots are not recited.

Applicant also asserts that the deposition device in the Henderson et al. reference is an atomic force microscope (AFM) tip, rather than the applicator pins of the claimed invention. However, this is not persuasive because Applicant has not recited structural limitations of the applicator pins such that they are distinguished from the device disclosed by Henderson et al. (Different portions of the AFM tip can be considered pins.)

Applicant also asserts that Eipel et al. disclose applying sample and reagents in liquid, not aerosol misted form and Church solely discloses inkjet deposition in which small drops of liquid, not an aerosol mist, are applied to a support. This is not persuasive because the Eipel et al. ink jet printer is capable of producing fine particles of liquid and thus is capable of producing an aerosolized mist. It is also noted that Applicant's claim 12 recite ink jet printheads, among other devices such as microsyringe

pumps, to be a device for aerosol mist generation. As to the arguments regarding the Church reference, the arguments are moot because the Church reference is no longer used in the grounds for rejection.

Applicant also argues that neither Engle et al. nor Tisone nor French et al. teach a system comprising two separate computer-controlled devices. This is not persuasive because Henderson et al. teach a computer and software for controlling the AFM tip (col. 9, lines 51-52 and col. 12, lines 33-36), and Tison teaches use of a microprocessor (i.e., computer) to control the syringe pumps (col. 7, lines 54-57), and Engle et al. (col. 2, lines 23-24) teach the motivation to provide a computer and software to control the Eipel et al. printer, as well as the syringe pumps of Tisone, and the obviousness in combining the references is described above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

LONG V. LE 11/18/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600